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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/080,920	Applicant(s) SIRHAN ET AL.	
	Examiner Sarah K Webb	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 11-18, 20-23, 26-28, 31, 32, 35, 45-49, 69, 71, 73, 74, 76, 79-85, 91, 97-101, 107, 132-144 and 147-155 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2-1-02</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,11-18,20-23,26-28,31,32,35,45-49,69,71,73,74,76,79-85,91,97-101,107,132-144 and 147-155.

DETAILED ACTION

Claim Objections

1. Claims 2, 101, 133, 137 and 139 are objected to because of the following informalities:

- a. "groove" is misspelled in line 5 of claim 2.
- b. A semicolon needs to be removed from line 2 of claim 101.
- c. "structure" is misspelled in line 2 of claim 133.
- d. Claim 137 – "the elongate body" should be replaced with "balloon structure shaft."
- e. "nickel" is misspelled in line 2 of claim 139.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 132-136, 138-142, 144, 147-149, and 155 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,195,978 to Schiffer.

Schiffer discloses a balloon catheter (Figure 1) that includes an inflation lumen (28) and a passage (30) that slidably receives an elongate body (18) (column 6, lines 11-16). After the tear strip (32) is removed, an axial groove is created, which communicates with the passage (30) and is capable of removably receiving the elongate body (18) (see Figure 3). As shown in Figures 4-6, the groove has two transverse ends (34, 36) when the strip (32) is removed.

Regarding claims 147-149, the groove extends a majority of the length of the catheter body, which is 100 to 160 cm (column 8, line 68). Schiffer explains that part of the shaft may be

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formed as a metal hypotube (column 9, line 6) and the shaft (22) has sufficient stiffness and pushability (column 5, line 62).

3. Claims 132-136, 138, 143, 144, and 155 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,395,335 to Jang.

Jang discloses a balloon catheter in Figure 3 that includes an inflation lumen (22), a passage (20) for slidably receiving an elongate body (50), or guide wire, and an axial groove (40) that removably receives the guide wire. The groove is formed as multiple intermittent grooves, or perforations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 11, 12, 16-18, 22, 23, 26-28, 35, 46-49, 69, 70, 73, 76, 79-85, 91, 97-101, 107, 132-136, 140-142, 144, and 147-155 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,655,746 to Daniels et al. in view of US Patent No. 5,135,535 to Kramer.

As best illustrated in cross section in Figure 3, Daniels discloses a balloon catheter that includes:

- a. A catheter body (68) with a guide wire (74) positioned in a guide wire lumen (70) and;
- b. A first balloon structure shaft (16) that has a passage (18) that receives the catheter body (68).

Daniels fails to form the balloon structure shaft (16) to have an axial groove in communication with the passage (18). Kramer discloses another balloon catheter that includes a first balloon structure shaft (11) that has a passage (14) that receives a guide wire (29). Kramer teaches that the shaft (11) should include an axial slit (23,24), or groove, along the length of the shaft proximal to the balloon. The groove (23,24) allows the balloon structure shaft (11,13) to be removed from the guide wire (29) while the guide wire (29) remains stationary in the body lumen. A replacement catheter may then be subsequently delivered over the guide wire (see column 6, lines 22-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an axial groove on the shaft of Daniels that communicates with the passage, as Kramer teaches that this allows the balloon structure shaft to be removed from the inner catheter and guide wire. This would allow a replacement catheter to be delivered over the inner catheter and guide wire so that multiple functions could be performed within the body lumen.

The catheter body (68) of Daniels has a circular shape and a lumen (70). As shown in Figure 5, an atraumatic tip (76) is positioned at the distal end of the catheter (68) (column 4, lines 55-57). Regarding claim 17, the distal end (16b) of the balloon structure (16) is distally tapered and has multiple lumens (see Figure 4). The catheter body (68) is formed from a polyethylene, a polymer (column 4, line 50). Regarding claims 22 and 26, the balloon structure includes a shaft (16) with an inflatable balloon (30) on the distal end and an inflation lumen (24)(column 3, lines 39-41). The passage (18) of the balloon structure (16) extends both proximally and distally of the balloon (30). Daniels explains that the balloon structure includes a sleeve (32) with an inflatable portion (30)(column 3, lines 50-60). Daniels gives the dimensions of the catheter body. The diameter of the catheter is 20-50 mils (column 4, line 37), which when converted to French (F), falls within the claimed range. The length is 40-140 cm (column 3, line

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33). Since the groove extends over a majority of the length of the catheter shaft, it would also have a length within the claimed range of 10-150 cm. Regarding claims 82-85 and 150-153 Kramer states that it is well known in the art of balloon catheters that guide wire diameters range from 0.008 to 0.035 inches (column 7, lines 28-30), or 0.02 – 0.09 cm. Therefore, it would have been obvious to form the passage and groove to accommodate a guide wire that has a size within this range.

5. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels in view of Kramer, and in further view of US Patent No. 5,830,227 to Fischell et al.

The modified Daniels device includes all the limitations of Fischell, except for a tapered distal end on the catheter. Fischell discloses another balloon catheter with a guide wire. Fischell teaches that the distal tip of the catheter body should be distally tapered between 1 and 5 cm so that the catheter can follow the guide wire more easily (column 1, line 42 and column 4, line 65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a tapered distal tip on the catheter of the modified Daniels device, as Fischell explains that this helps the catheter to follow the guide wire through tortuous paths.

6. Claims 20, 21, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels in view of Kramer, and in further view of Schiffer.

The modified Daniels device includes all the limitations of claims 21 and 71, except for forming the catheter as multiple bodies connected together. Schiffer teaches that a catheter body can have another tubular member, such as a hypotube, coupled to the proximal end for stiffening purposes (column 9, lines 5-7). Hypotubes are commonly formed of stainless steel and nickel-titanium alloys. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the catheter of the modified Daniels device as multiple connected bodies, as Schiffer teaches that this structure can add strength to the catheter body.

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7. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels in view of Kramer, as applied to claims 1 and 2 above, and further in view of Jang.

The modified Daniels device fails to form the groove as multiple intermittent grooves, but Jang teaches that the groove can be formed as multiple intermittent grooves, or perforations. It would have been obvious to substitute the continuous groove with a perforated groove. This is an obvious modification, since both types of grooves perform the same function.

Response to Arguments

8. Applicant's arguments, see page 11, filed 10/25/04, with respect to claim 83 have been fully considered and are persuasive. The objection to claim 83 has been withdrawn.

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that none of the references cited teach or suggest an axial groove that extends along a passageway in a balloon catheter shaft. Clearly, the references do contain teachings pertaining to an axial groove along a balloon catheter shaft that allows an inner elongate member to be removably received in a passageway. The structure taught by the references disclosed above is substantially similar to the structure disclosed and claimed by the applicant. Many of the references cited, such as Kramer and Schiffer, include teachings pertaining to the axial groove. The groove allows the balloon catheter to be removed from the inner member disposed in the passage. The groove can be formed in many different ways.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
12/29/04



JULIAN W. WOO
PRIMARY EXAMINER